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PATENT
Customer No. 22,852
Attorney Docket No. 3806.0505

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Marie-Francoise ROSIER-MONTUS *et al.*	Group Art Unit: 1632
Serial No.: 09/846,456	Examiner: T. Ton
Filed: May 2, 2001	
For: REGULATORY NUCLEIC ACID FOR THE ABC1 GENE, MOLECULES MODULATING ITS ACTIVITY AND THERAPEUTIC USES	

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

This paper is responsive to the Office Action mailed August 7, 2002, which set a shortened statutory period for response of one month. The Office has issued a restriction requirement, asserting that pending claims 1-56 are directed to thirteen allegedly separate and distinct inventions as follows:

Group I: Claims 1-38, drawn to isolated nucleic acids, recombinant vectors and host cells, classified in class 435, subclass 320.1, 325+, and 455;

Group II: Claims 39 and 40, drawn to non-human transgenic mammals, classified in class 800, subclass 3;

Group III: Claim 41, drawn to a method for screening a molecule that modifies transcription, classified in class 435, subclass 4;

Group IV: Claim 42, drawn to a kit for screening *in vitro* a molecule that modifies transcription, classified in class 435, subclass 4;

Group V: Claim 43, drawn to a method for screening *in vivo* a molecule that modifies transcription, classified in class 424, subclass 9.2;

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Group VI: Claim 44, drawn to a kit or pack for screening *in vivo* a molecule that modifies transcription, classified in class 424, subclass 9.2;

Group VII: Claims 45-50, drawn to "an undisclosed substance which modifies the transcription of a polynucleotide," which the Examiner does not classify;

Group VIII: Claim 51, drawn to a method of detecting impairment of ABC1 gene expression by detecting ABC1 mRNA, classified in class 435, subclass 4;

Group IX: Claim 52, drawn to a method of detecting impairment of ABC1 gene expression by sequencing, classified in class 435, subclass 4;

Group X: Claim 53, drawn to a kit for detecting impairment of the transcription of the ABC1 gene in an individual by quantifying the ABC1 mRNA, classified in class 435, subclass 4;

Group XI: Claim 54, drawn to a kit for detecting an impairment of the transcription of the ABC1 gene in an individual by sequencing, classified in class 435, subclass 4;

Group XII: Claim 55, drawn to a method for screening a molecule or substance which modifies the transcription of a polynucleotide of interest, classified in class 435, subclass 4; and

Group XIII: Claim 56, drawn to a kit or pack for screening a candidate molecule which modifies transcription of a polynucleotide of interest, classified in class 435, subclass 4.

Office Action, pages 2-3.

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Applicants are required to elect a group for examination on the merits. Office Action, page 15. To be fully responsive to the restriction requirement, Applicants provisionally elect group 1 (claims 1-38), with traverse.

There are two criteria that must be satisfied to make a proper restriction requirement:

(1) The inventions must be independent and distinct; and

(2) There must be a serious burden on the Examiner if restriction is required. MPEP 803. Applicants contend that the Examiner has failed to establish these criteria with respect to several of the proposed groups.

First, the Examiner contends that Groups I and II are directed to distinct products because:

> the nucleic acids of Invention I can be used to produce protein in vitro. The non human transgenic animals of Invention II can be used to observe gene function, or as models for disease or condition.

Office Action, pages 3-4. The Examiner does not present any evidence, however, as to why this difference imposes a serious burden. Thus, the Examiner has failed to establish one of the required elements for restriction.

Applicants contend that no burden is imposed by examining groups I and II together. The claims of group II depend from claims 1-34 of group I. Consequently, both groups are using identical nucleic acid sequences. Thus, a complete search of the nucleic acids of group I will produce all of the art that is relevant to both group I and group II. Accordingly, Applicants contend that no burden is imposed and the Examiner and respectfully request that groups I and II be rejoined for examination on the merits.

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A similar grounds for traversal is raised with respect to the products of group I, and the methods of their use and/or kits defined in groups III-VI and VIII-XIII. The claims of these groups all ultimately depend from one or more claims in group I. Due to this dependency, these method and kit claims of groups III-VI and VIII-XIII are using the same nucleic acids recited in the group I claims. Consequently, a complete search of the nucleic acids of group I will necessarily reveal any relevant art describing methods of using these nucleic acids, and kits containing the same. The Examiner has provided no evidence as to why such a search would be a burden. Accordingly, Applicants respectfully request that the methods defined in groups III-VI and VIII-XIII, as well as group II, be rejoined with group I for examination.

At the very least, Applicants remind the Examiner of the duty to rejoin the method claims, once the product claims are found allowable. The withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim must be rejoined. M.P.E.P. § 821.04.

For these reasons, Applicants respectfully request rejoinder of groups I-VI and VIII-XIII for examination on the merits. If necessary, please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: September 6, 2002

By: _____
M. Todd Rands
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